

# CMS Workshop on Coverage Guidance

Thursday, September 30<sup>th</sup> 2004  
11:00 AM – 1:00 PM (eastern time)

Section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires that the Secretary make available to the public the factors that are considered in making National Coverage Determinations (NCD) of whether an item or service is reasonable and necessary. This section further specifies that the Secretary shall develop guidance documents in a manner similar to the development of guidance documents under Section 701(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 371(h)).

Guidance documents give the public, particularly individuals or organizations that might request an NCD, detailed information on current interpretations of the statute, the NCD process, and related evaluation and decision-making factors.

CMS is holding this workshop to support the development of guidance documents and to ensure that CMS is appropriately engaging interested stakeholders early in this process. This workshop will serve to open up a discussion on the various factors that need to be incorporated into useful coverage guidance. CMS will host this workshop incorporating a panel discussion format that will be composed of both agency staff and non-agency members. CMS is looking for participation in this discussion from the stakeholder community that would be directly affected by the development of such guidance documents. An open comment and question period will follow input from both the panel and from CMS leadership.

This workshop will focus on the elements relevant to the development of CMS guidance documents in the future. There are several documents that are already either under development within the agency, or that are being considered for development.

Topics under consideration include:

- General Coverage Process
- Process for Requesting an NCD
- Types of Coverage “Categories”
- NCD implementation process
- Clinical Trials
- MCAC Process
- Differing Evaluation Process for Differing Technologies
- Difference Between Diagnostic and Therapeutic Decisions
- Molecular Diagnostic Imaging
- Treatments for Chronic Wounds
- Pharmacogenomic Testing

Outside of this special workshop, we invite public input regarding these and other possible topics for guidance documents, and a request for input has been posted at <http://www.cms.hhs.gov/coverage/guidance.asp> including information on how to submit comments. While these suggestions will be given consideration, CMS is not required to issue every guidance document on the list, and is not precluded from issuing other guidance documents not on the list.

**Forum Date and Time:**

Thursday, September 30<sup>th</sup>  
11:00 AM to 1:00 PM (eastern time)

**Participation Instructions:**

There are 2 ways to participate, by phone or "in-person".

**1. To participate by phone:**

Dial: **1-800-837-1935** & Reference Conference ID: **177759**

Persons participating by phone do not need to RSVP.

Note: TTY Communications Relay Services are available for the Hearing Impaired. For TTY services dial 7-1-1 or 1-800-855-2880 and for Internet Relay services click here <http://www.consumer.att.com/relay/which/index.html>.

A Relay Communications Assistant will help.

**2. To participate in-person:**

If you intend to participate in person, **RSVP is required:**

Please send a reply to this email by close of business (specific date info) to [SpecialODF@cms.hhs.gov](mailto:SpecialODF@cms.hhs.gov).

Please include the words “**COVERAGE WORKSHOP**” in the subject line of your message, and send us the following information:

- a) Your full name
- b) Your organization or representation
- c) Your contact information (phone and email)
- d) Special needs information

**Location information:**

Please arrive no later than 10:30 AM.

Photo identification is required at security points.

ADDRESS:  
CMS Single Site Building  
Multipurpose Room  
7500 Security Boulevard  
Baltimore, MD 21244

Map & Directions:

<http://cmsnet.cms.hhs.gov/hpages/ocsq/cmsdirections-north.htm>

ENCORE: 1-800-642-1687

“Encore” is a recording of this call that can be accessed by dialing 1-800-642-1687 and entering the Conf. ID # **177759**.

The recording begins on (specific day and date info), and expires after 4 business days.

For automatic emails of Open Door Forum schedule updates (Listserv registration) and to view Frequently Asked Questions please visit our website at:

[www.cms.hhs.gov/opendoor](http://www.cms.hhs.gov/opendoor).